



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb,  
David M. Knight and Scott Siegel

Application No.: 09/766,535 Group Art Unit: 1642

Filed: January 18, 2001 Examiner: K. A. Canella

Confirmation No.: 1000

Title: ANTI-TNF ANTIBODIES AND PEPTIDES OF HUMAN  
TUMOR NECROSIS FACTOR

CERTIFICATE OF MAILING OR TRANSMISSION	
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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or  
(First/Second submission after Final Rejection)

☐ under 37 CFR 1.97(b), or  
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☒ under 37 CFR 1.97(c) together with either:  
☐ a Statement under 37 CFR 1.97(e), as checked below, or  
☒ a \$180.00 fee under 37 CFR 1.17(p), or  
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:  
☐ a Statement under 37 CFR 1.97(e), as checked below, and  
☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.  
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
  - ☒ Copies of the cited references (AL8, AX12-AZ12 and AR13-AS13) are enclosed.
    - ☐ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
  - ☐ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
  - ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
  - ☒ The "concise explanation" requirement (non-English references) for reference AL8 under 37 CFR 1.98(a)(3) is satisfied by:
    - ☐ the explanation provided on the attached sheet.
    - ☐ the explanation provided in the Specification.
    - ☐ submission of the enclosed International Search Report.
    - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
    - ☒ the enclosed English language abstract for AL8.

☐ Applicant requests that the following non-published pending applications be considered:

Examiner's  
Initials

\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]  
\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]  
\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_\_  
Examiner

\_\_\_\_\_  
Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed.
- ☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- ☒ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[ ]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

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ATTORNEY DOCKET NO.

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APPLICATION NO.

09/766,535

**INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION**

April 14, 2004

(Use several sheets if necessary)

FIRST NAMED INVENTOR

Junming Le, *et al.*

FILING DATE

January 18, 2001

EXAMINER

K. A. Canella

CONFIRMATION NO.

1000

GROUP

1642

**FOREIGN PATENT DOCUMENTS**

		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO
	AL8	DE 42 02 665 A1	01/28/1992	Blitstein-Willinger	

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

AX12	Kassiotis, G. and Kollias, G., "Uncoupling the Proinflammatory from the Immunosuppressive Properties of Tumor Necrosis Factor (TNF) at the p55 TNF Receptor Level: Implications for Pathogenesis and Therapy of Autoimmune Demyelination," <i>J. of Exp. Med.</i> , 193(4):427-434 (2001).
AY12	Selmaj, K., <i>et al.</i> , "Anti-Tumor Necrosis Factor Therapy Abrogates Autoimmune Demyelination", <i>Ann. Neurol.</i> 30:694-700 (1991).
AZ12	Van Oosten, B. W., <i>et al.</i> , "Increased MRI activity and immune activation in two multiple sclerosis patients treated with the monoclonal anti-tumor necrosis factor antibody cA2," <i>Neurology</i> , 47(6):1531-1534 (1996) Abstract.
AR13	Van Oosten, B. W., <i>et al.</i> , "Treatment of multiple sclerosis with the monoclonal anti-CD4 antibody cM-T412: Results of a randomized, double-blind, placebo-controlled, MR-monitored phase II trial," <i>Neurology</i> , 49(2):351-357 (1997) Abstract.
AS13	Arnason, B. G. W., <i>et al.</i> , "TNF neutralization in MS: Results of a randomized, placebo-controlled multicenter study," <i>Neurology</i> , 53(3):457-465 (1999) Abstract.

EXAMINER

DATE CONSIDERED